UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to the TPP Trial Subclasses**	MDL No. 2875 Honorable Renée Marie Bumb, Chief Judge

TPP TRIAL DEFENDANTS' SUPPLEMENTAL BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION *IN LIMINE* NO. 16

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases **Page(s)**

Whether Third-Party Payor Plaintiffs ("TPPs") suffered any injury or damages is a focal point in this case. The Court has considered this issue at every stage of this lawsuit—ultimately deferring it to the jury in the summary judgment order. Unabashed, TPPs are now using this motion and their *Daubert* motion against Dr. Stiroh as a backdoor to relitigate this issue. The Court should allow evidence of alternative drugs because the evidence refutes TPPs' claims of injury. Courts deciding pharmaceutical cases involving TPPs like this one regularly permit such evidence and let the jury resolve competing expert testimony. Moreover, the TPPs mischaracterize the discovery record and ignore that Dr. Stiroh's opinions are based on admissible evidence.

I. TPPS' ALLEGED ECONOMIC INJURY IS DEFINED BY THE FACTS OF THIS CASE.

TPPs claim they suffered economic losses from purchasing valsartan-containing drugs ("VCDs") with nitrosamine impurities. To succeed, TPPs must prove that Defendants' actions deprived them of "the economic benefit of [their] bargain," a requirement for all their claims. *In re J&J Talcum Powder Mktg. & Sales Pracs. Litig.*, 903 F.3d 278, 281 (3d Cir. 2018); *see, e.g.*, *Ironworkers L.U. 68 v. Astrazeneca Pharms., LP*, 634 F.3d 1352, 1361 (11th Cir. 2011) ("Injury also is a necessary element of each of the plaintiffs' . . . consumer protection [claims] . . . [and] . . . common law fraud.").

TPPs' injury here is defined by three undisputed characteristics: (1) TPPs seek

economic loss damages, not personal injury damages; (2) the VCDs remained fully effective at treating hypertension; and (3) the VCDs have already been consumed, so TPPs are not seeking damages for unused VCDs sitting in a warehouse. The Third Circuit dealt with a similar situation in *Talcum*, another case involving an alleged failure to disclose a cancer risk associated with a product. 903 F.3d at 281. There, the Third Circuit discussed various economic injury theories that can be supported in these kinds of cases. *Id.* at 281 (noting that (1) plaintiff "does not allege that a product has caused her physical injury"; (2) plaintiff "does not allege that [the product] failed to adequately perform any of [its] functions"; and (3) "the complaint concerns a nondurable product that has already been consumed in its entirety").

The first theory is the "benefit of the bargain." It provides that damages are equal to the "difference in value between what was bargained for and what was received" if the product plaintiff ***received*** was worth less than expected. *Id.* at 283. The second is the "alternative product" theory. *Id.* at 282. In pharmaceutical cases, the "alternative product" theory typically takes either of two forms: the "excessive price" theory or the "quantity effect" theory.[1]

The "quantity effect" theory fits the mold of this case, as explained below.

[1] The "excessive price" theory is not at issue here. Under that theory, TPPs are entitled to damages equal to the "difference between what [the TPP] paid and the cost of an alternative medication" if they can prove that had they known about the undisclosed risk, they would have purchased another cheaper drug. *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 325 F.R.D. 529, 540 (D. Mass. 2017).

Under this theory, TPPs can recover the ***entire price paid*** if they prove that their members would not have been prescribed any alternative drugs in the but-for world. *See, e.g.*, *Sergeants Benevolent Ass'n Health and Welfare Fund v. Sanofi-Aventis U.S., LLP*, 20 F. Supp. 3d 305, 324 (E.D.N.Y.) (the "Quantity Effect Theory" applies where the TPPs paid for "prescriptions that would not have been issued but for the alleged misrepresentations");[2] *In re Avandia Mktg. & Sales Pracs. Litig.*, 804 F.3d 633, 636 (2015) (3d Cir. 2015) (similar).

TPPs brush aside cases that rely on alternative drugs evidence as inapplicable RICO cases. (ECF 2811 ("TPPs Br.") at 7.) Contrary to the TPPs' suggestion, the economic injury element discussed in these cases equally applies to fraud, express warranty, and consumer protection claims. *See, e.g.*, *In re Avandia Mktg. & Sales Pracs. Litig.*, 2013 WL 5761202, at *1, 5 (E.D. Pa. Oct. 23, 2013) (analyzing the "cognizable injury" element without distinguishing between RICO and consumer protection claims since injury is "a necessary element of each of Plaintiffs' claims").

II. TPPS' ECONOMIC INJURY THEORY ASSUMES NO PRESCRIPTION OF ALTERNATIVE DRUGS.

TPPs' allegations of economic harm should be "examine[d] . . . from a number of different angles" to determine their true nature. *Talcum*, 903 F.3d at 282; *see*

[2] TPPs falsely accuse Defendants of not "inform[ing] the Court that Judge Kugler had already explicitly rejected [*Sergeants*] in his summary judgment opinion." (TPPs Br. at 7.) The Court rejected *Sergeants*'s analysis of RICO causation, but did not consider the relevance of alternative drugs. (*See* ECF 2694 at 60-61.)

Kimca v. Sprout Foods, Inc., 2022 WL 1213488, at *8 (D.N.J. Apr. 25, 2022) (relying on plaintiffs' allegations to characterize the economic injury theory).

Here, TPPs' economic injury claims blur the lines between the "benefit of the bargain" and "quantity effect" theories. While TPPs contend their alleged harm should be exclusively examined through "benefit of the bargain" lenses (TPPs Br. at 1-2), their worthlessness theory assumes that TPPs would not have paid for any alternative hypertension drugs had the VCDs been unavailable and that they are therefore entitled to receive a full refund. Specifically, TPPs expressly allege that they "would not have purchased the VCDs had they known" about the presence of nitrosamines and that they should be awarded "damages in the amount of the purchase price of their medications." (ECF 1708 ¶¶ 631-32.) But this allegation begs the question: had the TPPs not paid for VCDs, would they have paid for some other blood pressure medications in the but-for world, or would they have left their members without medication to treat their hypertension?

TPPs' expert Dr. Conti does not answer this question. TPPs invite the Court to accept Dr. Conti's counterfactual premise underlying her damages calculations that there could be no supply for allegedly adulterated VCDs because they could not have been "lawfully sold" at the time.[3] (ECF 2040-3 ¶¶ 2, 7-8, 42.) But the VCDs

[3] TPPs' argument that reliance on alternative drugs is inconsistent with measuring damages at the point of sale is unavailing. (*See* TPPs Br. at 4.) In the but-for world, *(cont'd)*

were sold, so Dr. Conti's analysis depends on a counterfactual world where they were not and where TPPs would not have paid for any alternative drugs and are thus entitled to a full refund. This considers "only one half of the equation—the amount spent by TPPs for the at-issue VCDs, while failing to consider the other half—what [TPPs] would have paid in an alternative scenario." (ECF 2630-1 ¶¶ 33, 38-40.)

An award of damages under Dr. Conti's framework thus poses a real risk of violating the compensation principle, which is fundamental to the law of damages. *See Wicker v. Hoppock*, 73 U.S. 94, 99 (1867) ("The general rule is, that when a wrong has been done, and the law gives a remedy, the compensation shall be equal to the injury."). If Dr. Conti's methodology is applied without more, TPPs may ultimately end up keeping both the benefit of the VCDs (*i.e.*, satisfaction of their drug coverage obligations) and the full price paid, rather than only receiving compensation for their true loss. A windfall can be avoided ***only if*** there would have been no alternative prescriptions in the but-for world ***or if*** the VCDs did not allow TPPs to discharge their insurance obligations.

III. DEFENDANTS' EVIDENCE OF ALTERNATIVE DRUGS SEEKS TO PROVE THAT TPPS SUFFERED NO ECONOMIC HARM.

Defendants should be allowed to explain to the jury that compensatory damages are not warranted here because TPPs suffered no injury and Dr. Conti failed

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the payments for alternative drugs would have occurred *at the same point in time* as the payments for the at-issue VCDs were made in the real world.

to consider the cost of alternative drugs. *See Malibu Boats, LLC v. Skier's Choice, Inc.*, 2021 WL 1572477, at *4 (E.D. Tenn. Apr. 21, 2021) ("[Defendant's expert] is free to rebut the viability of [Plaintiff's] analysis and instead proffer his own theory for why Plaintiff is not entitled to lost profits."). At trial, Defendants' expert Dr. Stiroh will point out that "Dr. Conti does not identify any actual basis for economic loss to TPP Plaintiffs." (ECF 2630-1 ¶ 25.) At its core, Dr. Conti's error stems from her failure to "account for the specific role of TPPs" and to "measure . . . value from a TPP's standpoint." (*Id.*) In furtherance of this point, Dr. Stiroh will consider TPPs' unique posture and demonstrate that any award would result in a windfall for two important reasons that are anchored in the compensation principle. (*Id.* ¶ 34.)

First, Dr. Stiroh will testify that TPPs "received the value they expected from the at-issue VCDs." (*Id.* ¶ 32.) As TPPs, they "experience neither health benefits nor health risks." (*Id.*) When TPPs paid for the VCDs, they could logically expect to receive only "the value of fulfilling their financial commitments to plan members." (*Id.*) "The plan members alone receive the therapeutic value of effective treatment" and "incur the health risks, if any." (*Id.*) Dr. Stiroh will thus underscore that TPPs have proven no injury because their expert "does not identify or calculate any loss of value to TPPs in the fulfillment of their contractual obligations to plan members as a result of the at-issue VCDs." (*Id.*)

Second, building upon the first point, Dr. Stiroh will tell the jury that TPPs are "likely financially better off." (*Id.* ¶ 25.) Since the at-issue VCDs fulfilled TPPs' financial responsibilities at a lower cost compared to alternatives, "the fact that they did not have to pay more for alternative medications" means they suffered no economic harm. (*Id.*; *see* ECF 2046-1 ¶ 60.) As discussed above, all that matters for TPPs is the impact on their bottom line. If what TPPs received satisfied their coverage obligations at a cheaper cost than in the but-for world, then they were not deprived of the benefit of their bargain, and any damages would necessarily lead to a "windfall by restoring [TPPs] to a better position." (ECF 2630-1 ¶ 35.)

IV. THE COURT HAS DEFERRED THIS ISSUE TO THE JURY.

The parties have vigorously fought the issue of economic injury throughout this case—at the motion to dismiss stage, at class certification, and at summary judgment. (ECF 2694 at 57.) Each time, the Court refused to rule on the papers.[4] The Court should deny this motion consistent with the summary judgment order deferring this debate to the jury:

> ". . . these theories hinge on different legal perspectives and on genuinely disputed, material facts for the trial fact-finder . . . about the amount of damages—from none to the full amount TPPs reimbursed for the insureds' scripts. Their damages arguments not only go to the very heart of the parties' liability, but depend on strenuously debated

[4] While TPPs argue that the Court has already determined this issue (TPPs Br. at 4-5), the Court merely found that TPPs had "alleged sufficient injury . . . at the motion to dismiss stage." (ECF 775 at 20; *see* ECF 728 at 15.) The Court did not preclude Defendants from proffering their own theory of no economic injury.

damages theories." (ECF 2694 at 57.)[5]

The Court's decision to defer to the jury was consistent with *Blue Cross Blue Shield Ass'n v. GSK LLC*, 417 F. Supp. 3d 531 (E.D. Pa. 2019). There, the TPPs also brought common law fraud and express warranty claims, and alleged that "the adulterated drugs were worthless and had they known of the adulteration, they would not have included the drugs in their formularies." *Id.* at 537, 548. The TPPs' expert in that case was Dr. Conti. *Id.* at 557. The defendant manufacturer moved for summary judgment, asserting that Dr. Conti's "damages theory [was] impermissibly speculative . . . because the calculation fail[ed] to take into account the cost of therapeutic alternatives Plaintiffs would have had to provide." *Id.* at 558. Noting that the debate of worthlessness and alternatives "is necessarily a credibility dispute between the parties' experts," the court deferred the issue of whether the TPPs' "damages calculation should deduct the cost of therapeutic alternatives . . . [to] the jury." *Id.* at 557-59.[6] The Court should (again) do the same here.

[5] TPPs' judicial estoppel argument is nonsensical (TPPs Br. at 6) because Defendants did "not succeed in persuading the court" at summary judgment. (ECF 2778 at 18.)

[6] To be clear, a deduction would be inappropriate here. TPPs' damages theory follows an all-or-nothing approach. Either TPPs convince the jury they are entitled to a full refund or they get nothing because they proposed no methodology to award damages in between. Thus, if the jury agrees with Defendants that the cost of alternatives should have been considered, TPPs are entitled to zero damages.

V. DEFENDANTS' RELIANCE ON ALTERNATIVE DRUGS IS GROUNDED IN ADMISSIBLE EVIDENCE.

TPPs argue that alternative drugs evidence is speculative as "Defendants' experts do not identify the specific replacement therapies and associated prices therewith." (TPPs Br. at 10.) For starters, such arguments misconstrue the role of rebuttal experts and are routinely rejected by courts. (*See* ECF 2666 at 9.)

In any event, Defendants' argument is grounded in admissible evidence. At trial, TPPs themselves will admit that they would have had to pay for these alternative prescriptions. (ECF 2009-3, Ex. 29 at 208:5-13.) And Defendants' hypertension expert Dr. Flack will testify that because "patients . . . are typically dependent on their prescribed medication regimen," physicians "would have . . . prescribed . . . alternative antihypertensive drugs" in the but-for world. (ECF 2298-3 at 14-15.) He will further explain that drugs from the class were the most likely alternatives. (*Id.*) Finally, Dr. Stiroh will rely on academic literature, TPPs' actual costs following the recall (based on TPPs' transactional data), and IQVIA pricing data (the same pricing data relied upon by Dr. Conti) to provide an apples-to-apples comparison to Dr. Conti's calculations. (ECF 2046-1 ¶¶ 54-57, 60-64.)

VI. TPPS' *REDUCTIO AD ABSURDUM* ARGUMENT FAILS.

Using an inflammatory example, TPPs argue that allowing evidence of alternative products "would essentially create a rule of no damages." (TPPs Br. at 9.) TPPs' meritless argument ignores a long line of cases in which courts have

allowed alternative products evidence. (*See supra* at 2-3.) In any case, consumers in the TPPs' example would always have a personal injury claim, regardless of the availability of alternative products. And if the consumers did not consume the products, they would be entitled to a full refund because they received no benefit. Moreover, consideration of alternative drugs does not foreclose a TPP's damages claim if the TPP actually suffered a loss. (*See* ECF 2666 at 8.)

VII. TPPS MISCHARACTERIZE THE DISCOVERY RECORD.

TPPs' argument that it would be "unjust" for Defendants to introduce evidence of alternative drugs given that they "successfully opposed discovery regarding other hypertension medications" conflates two separate things. (TPPs Br. at 9-10.) The denied discovery was about Defendants' other products "using the same manufacturing processes, solvents, and testing as those for Valsartan API." (ECF 303 at 3.) TPPs' goal was to identify other products containing nitrosamines, so they could expand the scope of this lawsuit. (*See* Nov. 20, 2019 CMC Tr. at 16:21-24.) But that request has nothing to do with the evidence Defendants intend to present at trial, which includes evidence regarding alternatives to VCDs, TPPs' actual costs following the recall, and IQVIA price data.

CONCLUSION

The Court should deny TPPs' motion, allow Defendants to present alternative drugs evidence at trial, and let the jury resolve this competing expert evidence.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on August 23, 2024, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ *Alexia R Brancato*
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